1.0 Definition of the Procedure

Implantable cardioverter defibrillator (ICD) is an electronic device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver a shock to terminate these life-threatening arrhythmias for patients who are at risk. The device is connected to leads positioned inside the heart or on its surface. These leads are used to deliver electrical shocks, sense the cardiac rhythm and pace the heart, as needed. The various leads are tunnelled to a pulse generator, which is implanted in a pouch beneath the skin of the chest or abdomen (epicardial). These generators are typically a little larger than a wallet and have electronics that automatically monitor and treat heart rhythms recognized as abnormal. Newer devices are smaller and have simpler lead systems. They can be installed through blood vessels (transvenous), eliminating the need for open chest surgery.

When an implantable cardioverter defibrillator detects ventricular tachycardia or fibrillation, it shocks the heart to restore the normal rhythm. New devices also provide overdrive pacing to electrically convert a sustained ventricular tachycardia, and "backup" pacing if bradycardia occurs. They also offer a host of other sophisticated functions, such as storage of detected arrhythmic events and the ability to do "noninvasive" electrophysiologic testing. Implantable cardioverter defibrillators have been very useful in preventing sudden death in patients with known, sustained ventricular tachycardia or fibrillation.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

The N.C. Medicaid program covers implantable cardioverter defibrillator for patients who meet the following criteria:

3.1 Ventricular Tachycardia and Ventricular Fibrillation

1. documented episode of life threatening ventricular tachyarrhythmia, or cardiac arrest not associated with myocardial infarction
2. documented cardiac arrest due to ventricular fibrillation and not due to a transient or reversible cause
3. CAD, decreased LVF (EF <40%) after a previous myocardial infarction, and inducible sustained tachyarrthymia by programmed electrical stimulation

3.2 Prophylactic Implantation

Prophylactic implantation for patients who meet the following criteria:

1. previous myocardial infarction, at least 30 days prior
2. EF of 30% or less
3. CAD
4. patients who have not had coronary revascularization within the previous three months
5. absence of any co-morbid conditions that would hinder the benefit of the ICD implant such as, but not limited to:
    a. terminal cancer
    b. continual VT not controlled by medication
    c. psychosocial instability, i.e. non-compliance with medical regime
    d. other conditions which limit the life expectancy to one year or less

3.3 Dual Chamber ICD

Dual chamber ICD for patients who meet the following criteria:

1. criteria for traditional ICD as listed in **Sections 3.1 and 3.2**
2. two documented episodes of atrial fibrillation, or atrial tachycardia in the year prior, with EKG documentation
3. patients with chronic atrial fibrillation are **excluded**

3.4 Biventricular Pacing

Refer to Clinical Coverage Policy #11D for coverage criteria on biventricular pacing.

4.0 When the Procedure is Not Covered

Implantable cardioverter defibrillators are not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover traditional implantable cardioverter defibrillator for ventricular tachycardia and ventricular fibrillation or dual chamber ICD for ventricular arrhythmias and atrial fibrillation for any other conditions than those listed in **Section 3.0** including acute myocardial infarction**.**

4.1 History of or Active Substance Abuse
Must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

4.2 Psychosocial History
Psychosocial history that would limit ability to comply with medical care pre and post transplant.

4.3 Medical Compliance
Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this policy.

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
71/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered include:

33215	33216	33217	33225	33226	33240
33241	33243	33244	33245	33246	33249
93641					

D. Providers must bill their usual and customary charges.